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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/602,021	06/24/2003	Himanshu Brahmbhatt	060348-0104	7643

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EXAMINER

LANKFORD JR, LEON B

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 12/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/602,021

Applicant(s)

BRAHMBHATT ET AL.

Examiner

Leon Lankford

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-25 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-8, drawn to a method comprising subjecting a sample comprising minicells to density gradient ultracentrifugation, classified in class 435, subclass 261.
- II. Claims 9-12, drawn to a method comprising subjecting a sample comprising minicells to a condition that induces parent bacterial cells to adopt a filamentous form, then filtering said sample, classified in class 435, subclass 261.
- III. Claims 13-18, drawn to a method comprising subjecting a sample comprising minicells to density gradient ultracentrifugation, subjecting said sample minicells to a condition that induces parent bacterial cells to adopt a filamentous form, then filtering said sample, classified in class 435, subclass 261.
- IV. Claim 19, drawn to a method comprising subjecting a sample comprising minicells to density gradient ultracentrifugation, subjecting said sample minicells to a condition that induces parent bacterial cells to adopt a

filamentous form, then filtering said sample, and removing endotoxin from said sample, classified in class 435, subclass 261.

- V. Claims 20-24, drawn to a purified minicell preparation made by the process of Group I, classified in class 435, subclass 317.1.
- VI. Claim 25, drawn to a preparation of minicells, classified in class 435, subclass 317.1.

The inventions are distinct, each from the other because of the following reasons:

Groups I-IV are directed to methods that are distinct both physically and functionally, and are not required one for the other. Groups I and II are each drawn to a two-step method, and the method of Group I is not required for the method of Group II and vice versa. Group III and Group IV both require the steps of Groups I and II, but they result in a product that is patentably distinct from the products of the methods of Groups I and II. Group IV requires an endotoxin removal step that is not recited or suggested in the methods of Groups I-III; the product of Group IV is distinct from the product of Group III. Therefore, a search and examination of all four methods in one patent application would result in an undue burden, since the searches for the methods are not co-extensive, the classification is different, and the subject matter is divergent.

Inventions I-IV are related to Invention V as various processes of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and

materially different process (MPEP § 806.05(f)). In the instant case the product of Group V could be made by numerous processes not requiring the density gradient ultracentrifugation step of the methods of Groups I-IV. The composition of Group V is characterized physically in that it is purified from contaminants in the original sample; a sample of minicells comprising contaminants could be obtained, for example, by filtering the sample and resuspending the minicells in pure culture media. The product of Group II is separated from parent bacterial cells, which may be considered contamination. While Groups III and IV recite additional process steps, they comprise steps that separate minicells from contamination and, as such, yield products that are encompassed by Group V. Because these inventions are distinct for the reasons given above and the literature search required for Group V is not required for Groups I-IV, restriction for examination purposes as indicated is proper.

Inventions IV and VI are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the the product of Group VI could be made by numerous processes not requiring the steps of the method of Group IV. The composition of Group VI is characterized physically in that it is free from endotoxins; a sample of minicells free of endotoxins could be obtained without performing the density gradient ultracentrifugation and filament-inducing steps of Group IV, because

no degree of purity or separation is recited or implied in Group VI. Because these inventions are distinct for the reasons given above and the literature search required for Group VI is not required for Group IV, restriction for examination purposes as indicated is proper.

Invention VI is unrelated to Inventions I-III. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to a composition (Group VI) and four processes that do not yield the composition as claimed. Group V is drawn to a composition comprising minicells that is substantially free of endotoxins; as discussed above, Groups I-III do not recite or suggest the removal of endotoxins specifically from the sample comprising minicells. Because these inventions are distinct for the reasons given above and the literature search required for Group VI is not required for Groups I-III, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

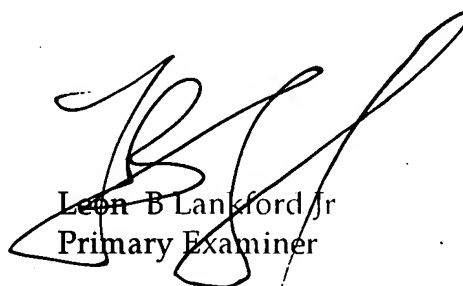
Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leon Lankford whose telephone number is 571-272-0917. The examiner can normally be reached on Mon-Thu 7:30-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Leon B Lankford Jr
Primary Examiner